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Attorney Docket No. 22058-544

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Warne, et al.

SERIAL NUMBER:

10/663,264

EXAMINER:

Not Yet Assigned

FILING DATE:

September 16, 2003

ART UNIT:

1614

For:

DELAYED RELEASE FORMULATIONS FOR ORAL

ADMINISTRATION OF A POLYPEPTIDE THERAPEUTIC AGENT

AND METHODS OF USING SAME

Mail Stop IDS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Transmitted herewith for filing in the present application are the following documents:

- 1. Supplemental Information Disclosure Statement (1 page), in duplicate;
- 2. Modified Form 1449/PTO (1 page), in duplicate;
- 3. Copies of Cited References: A12-15; B2-7; and
- 4. Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 22058-544. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted

David E Johnson Reg No. 41

Attorney for Applicants

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Date: January 6, 2004

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Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants make of record the documents listed on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are enclosed.

This Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action based on the merits in the above-identified case. Accordingly, no fee or certification is believed required. However, please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 Reference No. 22058-544.

Respectfully submitted,

David H. Johnson, Reg. No. 4/1,874

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Date: January 6, 2004

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PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE vork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Modified Form 1449/PTO **Application Number** 10/663,264 **Filing Date** September 16, 2003 **First Named Inventor** INFORMATION DISCLOSURE Warne STATEMENT BY APPLICANT **Group Art Unit** 1614 **Examiner Name** Not Yet Assigned (use as many sheets as necessary) Attorney Docket Number 22058-544 **U.S. PATENT DOCUMENTS** Class Cite Issue Date Name of Patentee(s) or Applicant(s) Filing Date
If Appropriate Exam U.S. Patent Sub Initials No. Document No. Class A12 4,518,584 85 05/21/85 Mark, et al. 424 A13 5,496,830 283 03/05/96 Shapiro, et al. 514 A14 5,631,219 6 05/20/97 Rosenthal, et al. 514 A15 5,846,958 114 12/08/98 Capizzi, et al. 514 U.S. PUBLISHED APPLICATION DOCUMENTS Name of Patentee(s) or Applicant(s) Exam Cite **U.S. Published Published** Class Sub **Filing Date** Initials No. Application No. Date If Appropriate **FOREIGN PATENT DOCUMENTS** Exam Cite **Foreign Patent Document** Name of Patentee(s) or Applicant(s) Date of **Translation** Initials No. Office Number **Publication** Yes **B2** wo 92/04455 GENETICS INSTITUTE, INC. 03/19/92 Yes В3 WO 96/19574 GENETICS INSTITUTE, INC. 06/27/96 Yes **B4** WO 99/37322 GENETICS INSTITUTE, INC. 07/29/99 Yes WO **B5** 00/74707 A2 GENETICS INSTITUTE, INC. 12/14/00 Yes **B6** WO 01/05355 A2 GENETICS INSTITUTE, INC. 01/25/01 Yes **B7** WO 02/22156 A2 GENETICS INSTITUTE, INC. 03/21/02 Yes OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Exam Cite Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc. Initials * a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed _ _, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications)

(continuation, continuation-in-part, and divisional applications).				
Examiner		Date		
Signature		Considered		
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.